DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2014

Sofradim Production
% Ms. Jennifer Brennan
Covidien LLC
Senior Manager, Regulatory Affairs
60 Middleton Avenue
North Haven, Connecticut 06473

Re: K142091
Trade/Device Name: Parietene™ Macroporous Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 1, 2014
Received: August 1, 2014

Dear Ms. Brennan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jiyoung Dang -S

On behalf of
Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142091

Device Name

Parietene™ Macroporous Mesh

Indications for Use *(Describe)*

The Parietene™ Macroporous Mesh is intended for the repair of hernias or other fascial deficiencies that require the addition of a reinforcing material.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K142091

510(k) Summary

Submitter Information

Name:	Sofradim Production (subsidiary of Covidien LLC)
Address:	116, avenue du formans 01600 Trevoux, France
Phone number	+33 (0)4 74 08 90 00
Fax number:	+33 (0) 4 74 08 90 02
Establishment Registration:	9615742
Name of contact person:	Jennifer Brennan Sr. Manager, Regulatory Affairs 60 Middletown Avenue North Haven, CT 06473 Phone: (203) 492-5346 Fax: (203) 492-5029
Date prepared:	July 21st, 2014

Name of device

Trade or proprietary name:	Parietene™ Macroporous Mesh
Common or usual name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
Classification panel:	General and Plastic Surgery (79)
Regulation:	21 CFR 878.3300
Product Code:	FTL
Legally marketed devices to which equivalence is claimed:	PROLENE™ Soft (Polypropylene) Mesh (K001122) Parietene™ Flat Sheet Mesh (K140941)
Reason for 510(k) submission:	To obtain market clearance of the Parietene™ Macroporous Mesh.
Device description:	The Parietene™ Macroporous Mesh is a non-absorbable synthetic surgical mesh made out of bi-dimensional monofilament polypropylene textile. The Parietene™ Macroporous mesh is offered in a flat sheet and pre-cut mesh. The pre-cut mesh facilitates the repair of inguinal hernias via the anterior approach using a tension free technique.

Parietene™ Macroporous Mesh

Intended use of the device: The Parietene™ Macroporous Mesh is intended for the reinforcement of soft tissue where weakness exists during surgical repair.

Indications for use: The Parietene™ Macroporous Mesh is indicated for the repair of hernias or other fascial deficiencies that require the addition of a reinforcing material.

Summary comparing the technological characteristics of the subject and predicate devices:

The subject Parietene™ Macroporous Mesh is substantially equivalent to the predicate device PROLENE™ Soft (Polypropylene) Mesh (K001122) in terms of design for the following technological characteristics:

- Indications
- Polypropylene textile performance
- Design: flat sheet meshes with similar shape and size.

The subject Parietene™ Macroporous Mesh is substantially equivalent to the predicate device Parietene™ Flat Sheet Mesh (K140941) in terms of design for the following technological characteristics:

- Polypropylene material
- Design: flat sheet meshes with similar shape and size.

Performance data:

Bench testing has been conducted in accordance with FDA's *Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh* issued March 2, 1999 to evaluate the performance characteristics of the subject Parietene™ Macroporous Mesh. The following mesh characteristics were assessed: mesh thickness, pore size, surface density, bursting strength, bursting distension, breaking strength, elongation at break, tear strength, suture strength.

The bench results demonstrate that the device is substantially equivalent to the predicate PROLENE™ Soft (polypropylene) Mesh (K001122).

Parietene™ Macroporous Mesh is made out of material that has been evaluated for biocompatibility in accordance with ISO 10993-1 for a permanent implant, a recognized standard by FDA (#2-179).

Parietene™ Macroporous Mesh shelf-life has been demonstrated by the stability results of the material and the ability of packaging to maintain product sterility per sealing.

In conclusion, all testing demonstrates that the subject Parietene™ Macroporous Mesh is substantially equivalent to the predicate Prolene™ Soft Mesh.